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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,067

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J. Stewart Young

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Attn: Noreen Johnson - IP Legal Department

2600 Sofamor Danek Drive

MEMPHIS, TN 38132

EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

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DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/695,067	Applicant(s) YOUNG ET AL.	
	Examiner JERRY CUMBERLEDGE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31, 33-46, 49, 51-55 and 57-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31, 33-46, 49, 51-55 and 57-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/10/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 10-12, 16-23, 29-31, 33, 34, 43, 53, 58-61 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167).

Crozet et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 3), said assembly comprising an interconnection element (Fig. 3) including a first body (Fig. 3, ref. 46) and a stud (Fig. 3, ref. 50), said first body having a first aperture (Fig. 3, near aperture through which ref. 62 extends) formed therein (Fig. 3) and said stud extending from the body (Fig. 3), said first aperture including an upper portion formed having a lobed shape (Fig. 3); a first rod connector (Fig. 3, ref. 30) including a first shaft (Fig. 3) terminating in a first rod engaging portion (Fig. 3, near ref. 18) and a lobe (Fig. 3, near ref. 62) extending laterally from an end of said first shaft (Fig. 3) and displaced axially along said first shaft from the spinal first rod engaging portion (Fig. 3); a second rod connector (Fig. 3, ref. 20) including a second shaft having a second body (Fig. 3, ref. 34) carried thereon, said second body having a second aperture formed therein (Fig. 3, ref. 40), said second aperture having the stud received therein (Fig. 3)(Fig. 2); and a fastener configured to engage with the stud (Fig. 3, ref.

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56). The first aperture defines a first axis (Fig. 3) extending through the first body (Fig. 3) and the stud is positioned to lie substantially orthogonal to the axis (Fig. 3). The first shaft exhibits a substantially round cross-sectional profile (Fig. 3, near ref. 28). The first rod engaging portion comprises a curved member (Fig. 3, near ref. 18) configured to at least partially encircle a spinal rod (Fig. 3). The first rod engaging portion comprises a threaded aperture (Fig. 2, ref. 24) extending into the curved member (Fig. 2). The first shaft is substantially straight (Fig. 3). The second shaft is curved (as it has various curves, Fig. 3). The first shaft is slidably received within the first aperture to allow the first rod engaging portion to be spaced from the second rod engaging portion at varying distances (Fig. 3). The second shaft is rotatable about an axis defined by the stud to vary an angle defined by the first shaft and the second shaft (Fig. 3). The first shaft and the second shaft are curved (Fig. 3, as they have various curves, Fig. 3). The second aperture of the second shaft is configured to allow the second shaft to pivot along the axis defined by the stud (Fig. 3). The first rod connector is rotatable about an axis defined by the first shaft (Fig. 3). The second body on the second shaft includes a lower surface, wherein engagement of the fastener to the stud urges the lower surface to contact the first shaft and clamp the first shaft in a first orientation relative to the second shaft (Fig. 4B). The first rod connector is rotatable about an axis defined by the first shaft (Fig. 3). The first rod connector is rotatable about an axis defined by the stud (Fig. 3). The second rod connector is rotatable about an axis defined by the stud (Fig. 3). The first shaft of the first rod connector and the second shaft of the second rod connector are curved (Fig. 3, as they have various curves). The assembly comprises a first spinal

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rod secured to the first rod engaging portion (Fig. 3, ref. 12) and a second spinal rod secured to the second rod engaging portion (Fig. 3, ref. 14), wherein the first spinal rod is positioned to lie non-parallel to the second spinal rod (Fig. 3). Engagement of the fastener to the stud secures the second rod connector in a selected orientation (Fig. 3). The first spinal rod defines a first plane and the second spinal rod is positioned to lie in a plane different from the first plane (Fig. 3). The first rod engaging portion comprises a hook (Fig. 3, near ref. 18) sized to at least partially encircle a spinal rod, said hook extending laterally from the first shaft in a first direction (Fig. 3) and wherein said lobe extends laterally from the first shaft along said first direction (Fig. 3). The assembly has a smooth exterior surface (Fig. 3). The first and second shafts are configured to nest with each other (Fig. 2). The stud is monolithic with said body (Fig. 3). The stud has a longitudinal axis, and said first shaft has a longitudinal axis, and said stud longitudinal axis is oblique to said first shaft longitudinal axis (Fig. 3). The first shaft and said second shaft are capable of pivoting with respect to each other between a first position in which said first shaft and said second shaft are substantially parallel, and a second position in which said first shaft and said second shaft define an interior angle between them that is less than 180 degrees (Fig. 2)(Fig. 3). The second aperture has a central axis (Fig. 3), and said second rod connector has a channel for accommodating a spinal rod (Fig. 3, near ref. 20), said channel having a longitudinal axis (Fig. 3), and said central axis and said longitudinal axis are perpendicular to each other (Fig. 3).

A method of treating a spinal defect, said method comprising: securing a first

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spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 1 (Fig. 1).

Crozet et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 3), said assembly comprising: a first rod connector (Fig. 3, ref. 18) including a first shaft terminating in a first body (Fig. 3, near ref. 18) having a channel therethrough (Fig. 3, channel which ref. 12 rests in); a second rod connector (Fig. 3, ref. 20) including a second shaft (Fig. 3) defining a longitudinal axis (Fig. 3) and terminating on a first end with a rod engaging portion (Fig. 3, near ref. 20) and on an opposite second end with a second body (Fig. 3, near ref. 36), said second body having a first aperture therein (Fig. 3, ref. 40) defining a first central axis (Fig. 3), said first end of said second rod connector also including a second aperture (Fig. 2, ref. 26) therein defining a second central axis (Fig. 3) positioned to lie at an angle to the first central axis (Fig. 3); an interconnection element (Fig. 3, ref. 44) having a third body (Fig. 3, ref. 46) that includes a third aperture (Fig. 3, aperture through which ref. 62 extends) therein for receiving a portion of said first shaft (Fig. 3) and a stud (Fig. 3, ref. 50) protruding upwardly from said third body (Fig. 3).

A method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 44 (Fig. 3).

Crozet et al. disclose a cross connector comprising an interconnection element including a first body (Fig. 3, ref. 44) having an aperture (Fig. 3, aperture through which ref. 62 extends) formed therein and a stud (Fig. 3, ref. 50) extending from said body

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(Fig. 3); a first spinal rod connector (Fig. 3, near ref. 18) including a first shaft (Fig. 3) having a proximal portion received within said aperture (Fig. 3) and a distal end carrying a first spinal rod engaging portion (Fig. 3, near ref. 18) configured to at least partially encircle a spinal rod (Fig. 3), said first shaft having a projection at an end of said proximal portion (Fig. 3, near ref. 62), a second spinal rod connector (Fig. 3, near ref. 20) having a second body (Fig. 3) on a proximal end (Fig. 3), a second spinal rod engaging portion on a distal end (Fig. 3, near ref. 20) and a second shaft extending therebetween (Fig. 3), wherein said body includes a second aperture (Fig. 3, ref. 40) having the stud received therein (Fig. 3)(Fig. 2); and a single fastener (Fig. 3, ref. 56) to secure the first and second spinal rod connectors to each other at a user defined orientation relative to each other (Fig. 2)(Fig. 3).

A method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 53 (Fig. 3).

Regarding claims 1 and 53, Crozet et al. disclose the claimed invention except for the first shaft and said lobe slideably received within the first aperture such that said lobe passes through said first aperture and upon rotation of said first rod connector said lobe prevents said first rod connector from being removed from said first aperture; the first aperture is non-circular; rotation of the first rod connector induces the lobe to contact said first body and inhibit removal of the first shaft from the first aperture; the projection being able to move through said aperture when said shaft is in a first orientation with respect to said aperture, and being unable to move through said

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aperture when said shaft is in a second orientation with respect to said aperture different from said first orientation. Crozet et al. do, however, disclose a fastening mechanism comprising lobe on the end of the first shaft in order to prevent the shaft from being removed from the first aperture (Fig. 3, ref. 62)(column 5, lines 55-65).

Lin discloses a fastening mechanism that comprises a lobed portion (Fig. 3, ref. 220) on a shaft portion (Fig. 3) and a non-circular aperture (Fig. 3 e.g. ref. 630, 730, 530, 430), the lobed portion passing through the aperture and, upon rotation, preventing the shaft from being removed from the aperture (column 3, lines 52-67).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the fastening mechanism of Crozet et al. with a fastening mechanism as taught by Lin in order to achieve the predictable result of preventing a shaft from being removed from an aperture.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) in view of Burgess et al. (US Pub. 2003/0114853 A1).

Crozet et al. in view of Lin disclose the claimed invention except for the first shaft being curved so as to be non-linear. Crozet et al. in view of Lin do, however, disclose the shafts extend between and connect the rod engaging portions of the device to one another (Crozet et al., Fig. 3), which in turn connects the spinal rods to one another (Crozet et al., Fig. 3).

Burgess et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 6) that comprises shafts that are curved (Fig. 6, refs. 84 and 82). The shafts are used to extend between and connect rod engaging portions of the device to one another (e.g. Fig. 1), which in turn connects spinal rods to one another (e.g. Fig. 1)(Fig. 6).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the shafts of Crozet et al. in view of Lin with curved shafts as taught by Burgess et al. in order to achieve the predictable result of extending between and connecting rod engaging portions of the device to one another, which in turn connects spinal rods to one another.

Claims 13-15, 24-28, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) in view of Sherman et al. (US Pat. 5,976,135).

Crozet et al. in view of Lin disclose the claimed invention except for a washer carried by the stud and positioned between the stud and the second aperture of the second rod connecting member.

Sherman et al. disclose a lateral connector assembly comprising a washer (Fig. 7, ref. 55) and the washer having splines (Fig. 7, ref. 60) and recesses (Fig. 6, ref. 58) and the second spinal rod connector having a lower surface (Fig. 11, ref. 72), which has a second set of splines (Fig. 11, ref. 82) which can matingly engage the splines of the washer, which allow the lateral connector to assume variable angular positions with

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respect to the washer (column 7, lines 1-19). The washer is made from a deformable material, since any material will deform when pressure is applied to it. The washer is capable of deforming when the fastener engages the stud. Engagement of the fastener can frictionally engage the washer to the first shaft of the first rod connector. The washer is capable of being carried by the stud and positioned between the stud and the second aperture of the second rod connecting member. This set-up enables the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the cross-connector assembly of Crozet et al. in view of Lin with a washer and the washer having splines and the second spinal rod connector with a lower surface, which has a second set of splines of Sherman et al., in order to allow the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19).

Claims 35, 36, 54, 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) in view of Shluzas (US Pat. 6,554,832 B2).

Crozet et al. in view of Lin disclose the claimed invention except for the assembly comprises an insert configured to at least partially encircle said first shaft, said insert disposed within said first aperture. The insert in combination with the first aperture define a ball and socket joint. An insert disposed within the second aperture, said insert

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configured to at least partially encircle said stud. The insert in combination with the second aperture define a ball and socket joint. The insert is substantially spherical. The insert is substantially cylindrical.

Shluzas discloses a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 2) that comprises an insert (Fig. 2, ref. 52) configured to at least partially encircle a shaft (Fig. 2, ref. 42) of a rod connecting member (Fig. 2) extending through a first aperture (Fig. 2, ref. 40) and positioned in a second body (Fig. 2, ref. 30) and in communication with a second aperture (Fig. 2, aperture through which ref. 58 is placed). The insert creates a ball and socket type-joint (Fig. 2)(Fig. 4)(column 2, lines 33-34), which allows for pivotal movement of the rod connecting members relative to each other (Fig. 4) (column 2, lines 33-34) (column 2, lines 36-39) (column 2, lines 49-54) and further allows one rod connector to be slidable relative to the other rod connector (column 2, lines 39-44). This pivoting and sliding allows for greater adjustability and individualization of the device.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Fig. 2 with an insert as taught by Shluzas, in order to create a ball and socket type-joint (Fig. 2)(Fig. 4)(column 2, lines 33-34), which would allow for pivotal movement of the rod connecting members relative to each other (Fig. 4) (column 2, lines 33-34) (column 2, lines 36-39) (column 2, lines 49-54) and would further allow one rod connector to be slidable relative to the other rod connector (column 2, lines 39-44). This pivoting and sliding would allow for greater adjustability and individualization of the device.

Claims 39-42, 44, 45, 49, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) in view of Shluzas (US Pat. 6,554,832 B2) in view of Papas (US Pat. 6,273,914 B1).

Crozet et al. in view of Lin in view of Shluzas disclose the claimed invention except for the assembly comprises an insert disposed within the second aperture, said insert configured to at least partially encircle said stud. The insert in combination with the second aperture define a ball and socket joint.

Papas discloses a spinal fixation device (Fig. 1) that comprises a connection (Fig. 2) that comprises an insert (Fig. 2, ref. 96) at least partially encircling a stud (Fig. 2, ref. 72) and a fastener engaged with the stud (Fig. 2, ref. 18). This connection allows for multiple degrees of freedom (column 4, lines 50-54).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the connection mechanism of Crozet et al. in view of Lin in view of Shluzas with a connection mechanism as taught by Papas, in order to allow for multiple degrees of freedom (column 4, lines 50-54).

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) in view of Troxell et al. (US Pat. 7,137,986 B2).

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Crozet et al. in view of Lin disclose the claimed invention except for the interconnection element includes a pair of flanges extending diametrically opposite each other circumferentially about the first body, and the second body includes a pair of internal flanges in the second aperture, wherein the flanges of said interconnection element interengage with the flanges of the second body. Crozet et al. in view of Lin, however, disclose a connection mechanism that comprises threaded portions in order to lock the components together (Crozet et al., Fig. 3, ref. 50)(Fig. 2)

Troxell et al. disclose a coupling assembly comprising an interconnection element (Fig. 3, near ref. 16, 74) that comprises flanges (Fig. 10, near ref. 80) that extend into an aperture (Fig. 3, aperture through ref. 24) in order to lock components of the coupling assembly together (Fig. 3).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the connection mechanism of Crozet et al. in view of Lin with a mechanism which utilizes flanges as taught by Troxell et al. in order to achieve the predictable result of locking components together.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) in view of Shluzas (US Pat. 6,554,832 B2) in view of Papas (US Pat. 6,273,914 B1) in view of Pfaiher (US Pat. 5,702,393).

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Crozet et al. in view of Lin in view of Shluzas disclose the claimed invention except for a lower surface of the insert includes recesses for engaging the first shaft of the first rod connecting member.

Pfaifer teaches a spinal device (abstract) that comprises an insert (Fig. 2, ref. 10) that comprises recesses (Fig. 2, ref. 17) on a lower surface (Fig. 2) as part of a snap-fit mechanism that is useful in locking the insert onto a rod (Fig. 4)(column 4, lines 8-17).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the insert of Crozet et al. in view of Lin in view of Shluzas with a snap-fit mechanism comprising recesses as taught by Pfaifer, in order to lock the insert to a spinal rod (Fig. 4)(column 4, lines 8-17).

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733